2018 Current Fiscal Year Report: Science Board to the Food and Drug Administration

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Science Board to the Food and Drug Administration	81

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	06/26/2018	06/26/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End
The Science Board heard a report from the Center for Biologics Evaluation and Research Program Review Subcommittee; heard about FDA's Patient Affairs Initiative; and discussed how the agency can leverage its existing tools and authorities, and work with stakeholders, to better address the complex scientific, public health and technology challenges it faces today.	04/23/2018	04/23/2018

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$3,358.00	$25,702.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$50,095.00	$52,119.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$3,281.00
18b(1). Travel and Per Diem to Non-Federal Members	$5,382.00	$16,706.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00

18c. Other(rents,user charges, graphics, printing, mail, etc.)	$14,394.00	$16,809.00
18d. Total	$73,229.00	$114,617.00
19. Federal Staff Support Years (FTE)	0.30	0.30

20a. How does the Committee accomplish its purpose?

The Science Board makes recommendations to the FDA specifically aimed at enhancing the science and research of the Agency. The Science Board to the Food and Drug Administration (Board) advises the Commissioner in discharging responsibilities as they relate to addressing specific and technically complex scientific issues of regulatory importance to FDA. The Board consists of a group of senior scientists with exceptionally accomplished backgrounds in evolving areas of new scientific research which will provide advice and further interaction between FDA, industry, academia, and other government agencies on technically complicated issues of regulatory importance. The Science Board has also completed an Agency-wide external peer review of scientific and research programs and will use the findings as a basis for future direction and guidance to the Agency.

20b. How does the Committee balance its membership?

Members are experts in the fields of food science, safety, and nutrition; chemistry; pharmacology; translational and clinical medicine and research; toxicology; biostatistics; medical devices; imaging; robotics; cell and tissue based products; regenerative medicine; public health and epidemiology; international health and regulation; product safety; product manufacturing sciences and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products. Members represent academia and industry and include one technically qualified member identified with consumer interests.

20c. How frequent and relevant are the Committee Meetings?

The Science Board met one (1) time in FY18 to discuss issues related to the science programs of the agency. In the FY18 meeting, the Science Board issued a report on the CBER Research Program, heard about FDA's Patient Affairs Initiative,and discussed how the agency can leverage its existing tools and authorities, and work with stakeholders, to better address the complex scientific, public health and technology challenges it faces today

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the Science Board are drawn from the highest scientific levels of academia, industry, research, and/or clinical practice. Their advice and guidance lend credibility to

the agency's science planning and its approach to specific scientific and technical issues.

20e. Why is it necessary to close and/or partially closed committee meetings?

This committee did not hold any closed meeting for FY18.

21. Remarks

No reports required for this committee in FY18. FDA opted not to fill vacancies on the committee this year.

Designated Federal Officer

Rakesh Raghuwanshi DFO, Office of the Chief Scientist

Committee Members	Start	End	Occupation	Member Designation
Afshari, Cynthia	01/01/2015	12/31/2018	Scientific Executive Director, Amgen Inc.	Special Government Employee (SGE) Member
Bahinski, Anthony	01/01/2015	12/31/2018	Global Head, Safety Pharmacology, GlaxoSmithKline	Special Government Employee (SGE) Member
Baldi, Rhondee	01/01/2017	12/31/2020	CONSUMER REPRESENTATIVE: Physician, Medical Director, Inovalon	Special Government Employee (SGE) Member
Goldman, Lynn	08/01/2011	12/31/2018	Dean and Professor of Environmental & Occupational Health. GW Univ	Special Government Employee (SGE) Member
Jenkins, Annalisa	01/01/2015	12/31/2018	CEO, PlaqueTec	Special Government Employee (SGE) Member
Kowalcyk, Barbara	06/24/2013	12/31/2019	Assistant Professor, The Ohio State University	Special Government Employee (SGE) Member
McLellan, Mark	01/01/2014	12/31/2019	Vice President of Research, Portland State University	Special Government Employee (SGE) Member
Nolan, Lisa	01/01/2014	12/31/2019	Professor and Dean, College of Veterinary Medicine, University of Georgia	Special Government Employee (SGE) Member
Psaty, Bruce	08/01/2011	12/31/2018	Professor, Medicine & Epidemiology, Cardiovascular Health Research Unit, University of Washington	Special Government Employee (SGE) Member
Reiss, Theodore	09/09/2014	12/31/2019	Vice PresidHead, Clinical Research and Development, Inflammation and Immunology, Celgene Corp.	Special Government Employee (SGE) Member
Sarwal, Minnie	01/01/2015	12/31/2018	Professor of Surgery and Director, Translational Transplant Research, University of California San Francisco	Special Government Employee (SGE) Member
Steele, Scott	01/01/2017	12/31/2020	Director, Regulatory Science Programs, University of Rochester	Special Government Employee (SGE) Member
Tosi, Laura	09/09/2014	12/31/2019	Director, Bone Health Program, Children’s National Medical Center, Washington DC	Special Government Employee (SGE) Member

Weaver, Connie	01/01/2015	12/31/2018	Distinguished Professor and Head, Department of Nutrition Science, Purdue University	Special Government Employee (SGE) Member
Xie, Xiang-Qun (Sean)	01/01/2015	12/31/2018	Professor of Pharmaceutical Sciences/Drug Discovery Institute, School of Pharmacy, University of Pittsburgh	Special Government Employee (SGE) Member
Yaszemski, Michael	03/20/2014	12/31/2019	Professor of Orthopedic Surgery and Biomedical Engineering andDirector of the Tissue Engineering and Biomaterials Laboratory, Mayo Clinic College of Medicine	Special Government Employee (SGE) Member

Number of Committee Members Listed: 16

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Science Board supports FDA's strategic priorities by (provide a narrative for your committee).

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓

Under $100,000 ☐
$100,000 - $500,000 ☐
$500,001 - $1,000,000 ☐
$1,000,001 - $5,000,000 ☐
$5,000,001 - $10,000,000 ☐
Over $10,000,000 ☐
Cost Savings Other ☐

Cost Savings Comments
The utilization of the Science Board enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the committee resulted in advice for the improvement of public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
137

Number of Recommendations Comments
The number of recommendations reflects the approximate number of recommendations provided to the agency from FY 2003 thru FY 2018.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
84%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, therefore, the Agency has the option of not implementing the advice. This number represents an approximation of the percentage of recommendations that the agency has fully implemented or plans to fully implement.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
9%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

When appropriate, information is made available to the public.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☑
Issued new regulation	☑
Proposed legislation	☑
Approved grants or other payments	☐
Other	☑

Action Comments

The Agency has reordered research priorities and made appropriate shifts in resources to acheive those priorities in response to Science Board recommendations.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☑
Other	☐

Access Comments

N/A